September 17, 2026

Zacks Small-Cap Research

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Longeveron Inc (LGVN-NASDAQ)

LGVN: Disappointing Results, but Options Remain Bright

LGVN is a clinical stage biotech company that is using cutting edge cellular technology to treat a rare heart disease and the impacts of aging. We place a value of $4.25 on LGVN using the discounted cash flow model.

Current Price (09/16/26)	$6.68
Valuation	**$4.25**

OUTLOOK

Longeveron is focusing on using its primary treatment, laromestrocel, to fight a rare pediatric heart birth defect that devastates families and continues to receive good FDA news regarding its treatment for Alzheimer's Disease, while also expanding its pipeline.

The company announced disappointing results from its pivotal HLHS trial but still has a valuable drug that has shown good prospect for treating numerous conditions.

SUMMARY DATA

52-Week High	**$11.60**
52-Week Low	**$4.84**
One-Year Return (%)	**-11.05**
Beta	**-0.25**
Average Daily Volume (sh)	**77,987**
Shares Outstanding (mil)	**3**
Market Capitalization ($mil)	**$21**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**10**
Insider Ownership (%)	**7**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2023 Estimate	**N/A**
P/E using 2024 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed**

ZACKS ESTIMATES

Revenue*
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	0.3 A	0.2 A	0.2 A	0.0 A	0.7 A
2024	0.5 A	0.5 A	0.8 A	0.6 A	2.3 A
2025	0.4 A	0.3 A	0.1 A	0.3 A	1.2 A
2026	0.4 A	0.3 A	0.8 E	0.9 E	2.4 E

Earnings per share*

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	-$0.22 A	-$0.27 A	-$0.28 A	-$0.25 A	-$1.02 A
2024	-$1.61 A	-$1.83 A	-$0.34 A	-$0.48 A	-$2.26 A
2025	-$0.34 A	-$0.33 A	-$0.39 A	-$0.31 A	-$1.29 A
2026	-$0.19 A	-$0.19 A	-$0.17 E	-$0.17 E	-$0.72 E

*quarterly numbers may not add to annual due to rounding and share issuance.

Update

Longeveron's September 16 announcement represents an important turning point for the company. The Phase 2b ELPIS II trial of laromestrocel in hypoplastic left heart syndrome, or HLHS, failed to meet its primary efficacy endpoint, a result that understandably caused a sharp reset in investor expectations. The primary endpoint measured the change in right ventricular ejection fraction at 12 months, and the difference between laromestrocel and the control group was essentially nonexistent: negative 0.7 percentage points, with a p-value of 0.8336. That is not a near miss and should not be portrayed as one. On the trial's prespecified primary efficacy measure, ELPIS II was unsuccessful.

That said, the announcement contained considerably more information than the headline suggests, and we believe it leaves Longeveron with potentially valuable assets and strategic options. Longeveron is developing laromestrocel, formerly known as Lomecel-B, a proprietary allogeneic mesenchymal stem cell therapy derived from the bone marrow of young healthy adult donors. The underlying idea is that these cells may exert anti-inflammatory, vascular, regenerative and tissue-repair effects rather than simply replacing damaged tissue. Longeveron has been attempting to leverage that biology across several diseases, creating what management has previously described as a "pipeline-in-a-product" strategy. Its current programs include HLHS, Alzheimer's disease, pediatric dilated cardiomyopathy and Aging-related Frailty.

Until yesterday, HLHS was the company's most advanced and arguably most important near-term value driver. That makes the ELPIS II failure significant. Investors should assume that the probability of a straightforward near-term regulatory filing for HLHS has declined materially, with the company noting it has a meeting scheduled with the FDA to discuss paths forward.

However, it would also be premature to conclude that the HLHS program has no remaining value. ELPIS II enrolled only 40 infants, an unavoidable challenge in studying an extremely rare pediatric disease. Although the primary endpoint failed, several exploratory clinical observations moved numerically in favor of laromestrocel. During the first 12 months, there were no deaths among treated patients compared with one death in the control group. During longer-term follow-up of as much as five years, there was one transplant-free survival event among 17 laromestrocel-treated patients compared with two among 21 control patients. Most interestingly, adjudicated Major Adverse Cardiovascular Events (MACE) totaled 12 in the treated group versus 19 in the untreated group, approximately 31% fewer events.

Those findings should be interpreted carefully. The MACE analysis was not statistically significant, hospitalization burden was similar between the groups, and exploratory endpoints cannot retroactively turn a failed primary endpoint into a successful trial. Nevertheless, reducing major cardiovascular complications, transplantation or mortality would arguably matter considerably more to families and physicians than improving an imaging measurement if such an effect could eventually be demonstrated conclusively.That distinction may become central to Longeveron's discussions with the FDA mentioned above.

The safety findings are also worth emphasizing. No new safety signals emerged, and investigators did not attribute any treatment-emergent adverse events or serious adverse events to laromestrocel. Across Longeveron's clinical programs, approximately 644 participants have now received the therapy. For a cellular treatment platform intended for use in very vulnerable populations, including infants and elderly patients, an expanding safety database is an important asset.

We believe the broader investment argument is still interesting when attention shifts away from HLHS.

Longeveron has generated some of its strongest clinical evidence in Aging-related Frailty. Earlier this year, Phase 2b results published in Cell Stem Cell showed that intravenous laromestrocel improved physical function compared with placebo. At nine months, the treatment produced a 63.4-meter improvement relative to placebo in the six-minute walk test, with a p-value of 0.0077. This was not merely a numerical trend; it was a statistically significant result on a clinically understandable functional endpoint.

That research subsequently helped Longeveron become one of the finalists in the XPRIZE Healthspan competition, selected from more than 600 applicants. The company received a $1 million Milestone 2 award and remains eligible to compete for a grand prize of as much as $81 million, although reaching that stage requires successful completion and financing of the competition's required clinical trial.

Longeveron has also already completed Phase 1 and Phase 2 work in Alzheimer’s disease and has received both RMAT and Fast Track designations from the FDA for that program. Importantly, the company previously aligned with the FDA regarding the design of a potential Phase 3 trial. Data presented this summer also suggested that laromestrocel may reduce neuroinflammation in key areas of the brain, adding biological support to the clinical program.

The challenge is financial. A Phase 3 Alzheimer’s trial is well beyond what Longeveron can realistically finance independently at its present size. Management has been seeking strategic partners and non-dilutive funding for that program.

This brings us to what may now be the most important portion of yesterday’s announcement: Longeveron has begun a formal review of alternatives designed to maximize shareholder value and intends to engage an investment bank as strategic advisor. The company is simultaneously implementing cash-conservation measures.

Longeveron possesses more than a single failed clinical trial. It owns a cell-therapy platform with human clinical data across several indications, a growing safety database, FDA regulatory designations, intellectual property, manufacturing know-how and published clinical research. The Alzheimer’s program has RMAT and Fast Track status, while the HLHS program has historically carried Orphan Drug, Fast Track and Rare Pediatric Disease designations. Across its development programs, laromestrocel has received five FDA designations.

These assets could potentially be worth more to a larger biotechnology or pharmaceutical company with the capital necessary to conduct late-stage trials than they are inside a small company attempting to finance several programs simultaneously.

In our view, without a partnership, asset monetization or additional financing, Longeveron would face additional capital requirements. That creates dilution risk for existing shareholders and represents arguably the most significant near-term financial risk following the ELPIS II result.

The investment case for LGVN has consequently changed substantially.

Before ELPIS II, the story centered heavily on the possibility that positive Phase 2b HLHS data could support a relatively direct regulatory path toward commercialization. That scenario is no longer the base case. In our view, LGVN is now better viewed as a deeply discounted biotechnology platform with several pieces of clinical and regulatory optionality.

Laromestrocel has demonstrated a broad safety profile in hundreds of patients. Aging-related Frailty has produced statistically significant Phase 2b functional data and external validation through publication and the XPRIZE competition. The Alzheimer’s program has FDA RMAT and Fast Track designations and a potential Phase 3 pathway. HLHS itself may still have some value if the

exploratory cardiovascular outcomes generate sufficient regulatory interest to justify another development strategy.

The risks, however, are substantial. The company remains a clinical-stage biotechnology business with minimal commercial revenue. ELPIS II failed its primary endpoint. The exploratory cardiovascular findings were not statistically significant. The company will need more capital unless a strategic transaction or meaningful non-dilutive funding occurs. Additional equity financing could materially dilute current shareholders. There is also no guarantee that the FDA will identify a practical path forward in HLHS or that a pharmaceutical partner will emerge for Aging-related Frailty or Alzheimer's disease. For that reason, we believe LGVN today is a substantially more speculative investment than it appeared immediately before the ELPIS II readout and have reduced the valuation of LGVN as a result.

This announcement does not necessarily mean that Longeveron's underlying technology has failed. It means that laromestrocel failed to improve one specific cardiac-function endpoint in one small trial in one exceptionally difficult pediatric disease. Other clinical programs have generated different outcomes, including statistically significant results in Aging-related Frailty.

The next several developments may therefore be unusually important. Investors should watch for the FDA's reaction to the complete ELPIS II dataset, additional analyses of cardiovascular events and survival, details of Longeveron's cost reductions, progress in the XPRIZE Healthspan program, advancement or partnering of the Alzheimer's program, and—perhaps most importantly—the outcome of the newly announced strategic review. The risks of investing in LGVN have increased, but we believe the opportunity for shares to gain value in a meaningful way also exists.
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